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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/007,093	01/14/1998	NAVEEN N. ANAND	1038-765-MIS	4495

7590

11/04/2002

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EXAMINER

SCHWADRON, RONALD B

ART UNIT

PAPER NUMBER

1644

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/007,093

Applicant(s)  
Anand et al.

Examiner  
Ron Schwadron, Ph.D.

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 5-11, 27, and 28 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-11, 27, and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

1. Claims 5-11,27,28 are under consideration.

## RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The rejection of claims 5-9,11,27,28 under 35 U.S.C. 103(a) as being unpatentable over Barber (US Patent #4,950,480), in view of Baier et al. (*J. Virol.* 69(4):2357-2365, 1995) for the reasons elaborated in the previous Office Action is withdrawn in view of the 1.131 Declaration filed 5/1/2002.

4. Claim 10 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (US Patent #4,950,480), in view of Baier et al. (*J. Virol.* 69(4):2357-2365, 1995) for the reasons elaborated in the Office Action mailed 1/6/2000.

The declaration filed on 1.131 under 37 CFR 1.131 is ineffective to overcome the cited references.

As per noted in the previous Office action, the invention of claim 10 was not disclosed in the first filed 1.131 declaration, and it is also not disclosed in the 1.131 Declaration filed 5/1/2002. Applicant has not addressed this issue.

5. The rejection of claims 5-9,11,27,28 under 35 U.S.C. 103(a) as being unpatentable over Barber (US Patent #5,194,254) in view of Baier et al. (*J. Virol.* 69(4):2357-2365, 1995) for the reasons elaborated in the previous Office Action is withdrawn in view of the 1.131 Declaration filed 5/1/2002.

6. Claim 10 stands rejected under 35 U.S.C. 103 as being unpatentable over Barber (US Patent #5,194,254) in view of Baier et al. (*J. Virol.* 69(4):2357-2365, 1995) for the reasons elaborated in the previous Office action.

The declaration filed on 1.131 under 37 CFR 1.131 is ineffective to overcome the cited references.

As per noted in the previous Office action, the invention of claim 10 was not disclosed in the first filed 1.131 declaration, and it is also not disclosed in the 1.131 Declaration filed 5/1/2002. Applicant has not addressed this issue.

7. The rejection of claims 5-9,11, 27 and 28 under 35 U.S.C. § 103 as being unpatentable over Baier et al. (*J. Virol.* 69(4):2357-2365, 1995) for the reasons elaborated in the previous Office Action is withdrawn in view of the 1.131 Declaration filed 5/1/2002.

8. Claim 10 is rejected under 35 U.S.C. § 103 as being unpatentable over Baier et al. (*J. Virol.* 69(4):2357-2365, 1995) for the reasons elaborated in paragraph 24 of the Office Action mailed 1/6/2000.

The declaration filed on 1.131 under 37 CFR 1.131 is ineffective to overcome the cited references.

As per noted in the previous Office action, the invention of claim 10 was not disclosed in the first filed 1.131 declaration, and it is also not disclosed in the 1.131 Declaration filed 5/1/2002. Applicant has not addressed this issue.

9. Claims 5-9,11, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (WO 94/06469).

Altman et al. teach a fusion protein containing an antibody binding domain which binds a surface determinant on an APC and an immunogenic HIV-derived epitope (see claim 1 and page 6). Altman et al. teach that the "antibody binding domain" can be an entire intact antibody molecule (see page 7, line 3-8). Altman et al. teach that the epitope can be 15 amino acids (see page 8). The conjugate has increased immunogenicity in comparison to the native epitope (see page 4, lines 9 and 10). Altman et al. teach that the antigenic epitope can be directly linked to both chains of the antibody molecule (see page 10, last sentence and page 11, first six lines). Altman et al. do not teach that the peptide is linked to the c-terminal end of the intact antibody molecule.

Altman et al. teach an Fab construct where the antigenic peptide is linked to the c-terminal end of the constant region of the light and heavy chain of the Fab (see Figure 1). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Altman et al. teach a fusion protein containing an antibody binding domain which binds a surface determinant on an APC and a HIV-derived epitope (see claim 1 and page 6) and Altman et al. teach that the peptide can be attached at the c-terminal end of the constant regions of light and heavy chains of an antibody fragment that contains constant regions (See figure 1). One of ordinary skill in the art would have been motivated to do the aforementioned because Altman et al. teach that the peptide can be attached at a c-terminal end of the constant regions of light and heavy chains of an antibody fragment and an intact antibody molecule would also possess c-terminal constant regions. Altman et al. teach the claimed pharmaceutical composition (see claim 14).

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (WO 94/06469 as applied to claims 5-9, 11, 27 and 28 are above, and further in view of Barber et al. (US Patent 5,194,254).

The previous rejection renders obvious the claimed invention except for use of multiple different antigens. Barber et al. teach antibody/immunogenic peptide conjugates where the conjugate contains multiple differing antigens (see column 5, first complete paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous renders obvious the claimed invention except for of multiple different antigens whilst Barber et al. teach antibody/immunogenic peptide conjugates where the conjugate contains multiple differing antigens (see column 5, first complete paragraph). One of ordinary skill in the art would have been motivated to do the aforementioned because Barber et al. teaches that such conjugates can be used to elicit antibody responses against multiple different antigens (see column 5, first complete paragraph). The art recognized that HIV contains multiple different antigens and that generating responses against said antigens would be beneficial.

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile

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transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1600 1600

Ron Schwadron, Ph.D.

Primary Examiner

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